

**REMARKS**

Claims 1, 2, 5, 7, 8, and 10-20 are pending in this application. Non-elected claims 2, 16, and 19 are withdrawn from consideration by the Examiner. By this Amendment, claims 1, 2, 5, 11, 14, and 19 are amended, claim 20 is added, and claims 3, 4, 6, and 9 are canceled. Support for the amendments to the claims and new claim 20 may be found, for example, in the specification at page 1, lines 8-13, page 2, lines 22-32, and page 6, lines 33-36, and in the claims as originally filed.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

**I. Allowable Subject Matter**

Applicants appreciate the indication that claim 14 contains allowable subject matter, but stands objected to as being dependent upon a rejected base claim. However, Applicants respectfully submit that claims 1, 2, 5, 7, 8, and 10-20 are also allowable for at least the reasons discussed below.

**II. Rejection Under 35 U.S.C. §112, Second Paragraph**

The Office Action rejects claims 1 and 5 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection.

By this Amendment, claims 1 and 5 are amended to overcome the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**III. Rejection Under 35 U.S.C. §102**

The Office Action rejects claims 1, 3, 5-7, 12, 13, 15, 17, and 18 under 35 U.S.C. §102(a) & (e) as being anticipated by WO 02/087326 A1 to Huth et al. ("Huth").<sup>1</sup> By this

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<sup>1</sup> Applicants respectfully point out that Huth qualifies as a §102(b) reference because it was published (November 7, 2002) more than one year before the effective U.S. filing date (December 26, 2003) of this application.

Amendment, claims 3 and 6 are canceled, rendering their rejection moot. As to the remaining claims, Applicants respectfully traverse the rejection.

By this Amendment, claim 1 is amended to incorporate the non-rejected subject matter of claim 9, rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**IV. Rejection Under 35 U.S.C. §103**

The Office Action rejects claims 1, 3, 5-13, 15, 17, and 18 under 35 U.S.C. §103(a) as having been obvious over Huth, U.S. Patent No. 6,806,243 to Hozumi et al. ("Hozumi"), and U.S. Patent No. 7,320,870 to Laurie et al. ("Laurie"). By this Amendment, claim 1 is amended to incorporate the subject matter of claims 3, 6, and 9, rendering their rejection moot. To the extent that the rejection is deemed to apply to the remaining claims, Applicants respectfully traverse the rejection.

By this Amendment, claim 1 is amended to be directed to a process to improve viability, growth, and differentiation of corneal epithelial cells that comprises "applying an ophthalmic medicine or ophthalmic solution comprising a complex nutritive base to an external surface of a cornea of an eye of a human or an animal, the base consisting of a multiplicity of amino acids, vitamins, trace elements, and metallic salts." Huth does not disclose and would not have rendered obvious, individually or in combination, the claimed method for at least the following reasons.

Huth is directed to compositions (and associated methods) for caring for contact lenses and eyes in which the compositions include a liquid aqueous medium and a vitamin derivative component present in an amount effective as a surfactant. See abstract. As a surfactant, Huth discloses that the vitamin derivative component should be present in an amount effective to at least assist in removing deposits (e.g., debris) from contact lenses or the eyes. See page 6, line 24 to page 7, line 10 and page 10, lines 16-29. Besides acting to

remove deposits, the vitamin derivative component provides the additional benefit of being metabolized into a nutritionally beneficial vitamin upon absorption. See page 2, line 30 to page 5, line 16 and page 10, lines 5-15. However, Huth is entirely silent on a process to improve viability, growth, and differentiation of corneal epithelial cells (as claimed in claim 1).

Additionally, Huth does not disclose and would not have rendered obvious applying an ophthalmic medicine or ophthalmic solution comprising a complex nutritive base to an external surface of a cornea of an eye of a human or an animal in which the base consists of a multiplicity of amino acids, trace elements, and metallic salts in addition to vitamins. Huth only discloses adding reducing agents, such as amino acids and certain types of metallic salts, when an oxidative disinfectant, such as hydrogen peroxide, is present in the composition. See page 18, line 28 to page 19, line 19.

Although Huth discloses both "out-of-eye" compositions for applying to contact lenses that are not in contact with ocular tissue and "in-the-eye" compositions that are applied directly to the eyes (or contact lenses that are in contact with the eyes), an ordinarily skilled artisan would understand that oxidative disinfectants are only to be used in "out-of-eye" compositions. See page 8, line 24 to page 10, line 4. Compositions having oxidative disinfectants are not suitable for being applied directly or indirectly to the external surface of the cornea of the eye because such oxidative disinfectants are known to cause damage to ocular tissue. Instead, such "out-of-eye" compositions are used to clean contact lenses that are not in contact with ocular tissue and the compositions are typically then removed from the contact lenses by washing before the contact lenses are positioned in the eye.

In this context, Huth discloses that "[w]hen an oxidative disinfectant is used in the present invention, a reducing or neutralizing component in an amount sufficient to chemically reduce or neutralize substantially all of the oxidative disinfectant, for example, hydrogen

peroxide, present is employed." See page 18, lines 28-32. Such "[r]educing components include . . . amino acids and . . . pyrosulfites and dithionites such as the alkali metal salts or alkaline earth metal salts of sulfurous acid, pyrosulfurous acid and dithionious acid, e.g., lithium, sodium, calcium and magnesium salts and mixtures thereof." See Huth at page 19, lines 4-18.

Accordingly, an ordinarily skilled artisan would not provide an oxidative disinfectant, such as hydrogen peroxide, to an "in-the-eye" composition because of the risk that it would damage the eye. Thus, an ordinarily skilled artisan would not provide a reducing agent, such as certain amino acids and metallic salts disclosed by Huth, to an "in-the-eye" composition because an oxidative disinfectant would not be present to reduce. Huth therefore does not disclose and would not have rendered obvious applying an ophthalmic medicine or ophthalmic solution to an external surface of a cornea of an eye of a human or an animal--i.e., applying an "in-the-eye" medicine or solution--in which the medicine or solution comprises a complex nutritive base that consists of a multiplicity of amino acids, vitamins, trace elements, and metallic salts, as required by claim 1.

Hozumi and Laurie fail to cure the deficiencies of Huth with respect to claim 1. Additionally, Hozumi discloses an ophthalmic solution that comprises a biguanide and/or quaternary ammonium salt germicidal/preservative component, an amino-acid-based component, sodium chloride, and phosphate. See column 3, lines 1-14. Hozumi discloses that the amino-acid-based component may comprise proline to assure an excellent germicidal effect. See column 4, lines 1-14. Thus, an ordinarily skilled artisan would not have included proline as a promoter of neocollagen synthesis in a process to improve viability, growth, and differentiation of corneal epithelial cells in view of the teachings of Hozumi because Hozumi

does not teach that proline promotes neocollagen synthesis.<sup>2</sup> The Office Action asserts that Laurie discloses hyaluronic acid as a viscosity agent. See Office Action at page 6. However, the Office Action fails to set forth any specific reason or rationale for why an ordinarily skilled artisan would have modified a composition disclosed by Huth to include a viscosity agent. Rather, the Office Action only asserts that it could be used to adjust the viscosity. See page 6. Moreover, the method of claim 11 provides hyaluronic acid to an ophthalmologic solution as a hydrating agent and not to adjust its viscosity.

For at least these reasons, the applied references would not have rendered obvious claim 1. Claims 5, 7, 8, 10-13, 15, 17, and 18 depend from claim 1 and, thus, also would not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

**V. Rejoinder**

Applicants respectfully request rejoinder of non-elected claims 2, 16, and 19. Unity of invention exists between claim 1 and claim 2 (from which claims 16 and 19 depend) because they share a special technical feature. Specifically, claims 1 and 2 are both directed to processes that involve applying a composition that comprises the recited complex nutritive base to (a) an external surface of a cornea of an eye of a human or an animal (claim 1), or (b) to an item that is designed to come into external contact with a cornea of an eye of a human or an animal (claim 2). For the reasons discussed above with respect to claim 1, directly or indirectly applying a composition with the complex nutritive base to an external surface of a cornea of an eye of a human or an animal defines a contribution over the art, establishing unity of invention between claims 1, 2, 16, and 19.

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<sup>2</sup> The Office Action asserts that water is a promoter of neocollagen synthesis. See page 5. Applicants respectfully submit that water is not an art-recognized promoter of neocollagen synthesis, and thus this assertion is incorrect and without support.

Accordingly, withdrawal of the restriction requirement and rejoinder, examination, and allowance of non-elected claims 2, 16, and 19 are respectfully requested.

**VI. New Claim**

By this Amendment, new claim 20 is presented. Claim 20 depends from claim 1 and, thus, distinguishes over the applied references for at least the reasons discussed above with respect to claim 1. Accordingly, prompt examination and allowance of claim 20 are respectfully requested.

**VII. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Request for Continued Examination

Date: December 28, 2009

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